Neurocrine Biosciences Announces Completion of Enrollment in Phase 3 KINECT-HD Study Evaluating Valbenazine for Chorea in Huntington Disease

August 5, 2021

- Top-Line Readout of Clinical Study Results Anticipated by the End of 2021
- Initiating Expanded Enrollment to New Participants in Open-Label Extension Study KINECT-HD2

SAN DIEGO, Aug. 5, 2021 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX), in collaboration with the Huntington Study Group, today announced the completion of patient enrollment for its Phase 3 (KINECT-HD) clinical study evaluating the efficacy, safety and tolerability of valbenazine, a selective, orally active vesicular monoamine transporter 2 (VMAT2) inhibitor being investigated as a once-daily treatment in adults with chorea in Huntington disease. A top-line data readout of the clinical study results is anticipated by the end of 2021.

"This milestone reflects the progress that we have made in advancing valbenazine as a potential treatment for people living with chorea in Huntington disease and we look forward to sharing top-line results later this year," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "I'd like to thank our partners at the Huntington Study Group, the Clinical Trials Coordination Center at the University of Rochester, New York, the KINECT-HD investigative staff, and especially the patients and families for their commitment and perseverance in completing enrollment in the face of all the challenges posed by the pandemic."

Participants who have completed KINECT-HD can enroll in KINECT-HD2, an open-label extension study to evaluate the long-term safety and tolerability of valbenazine for the treatment of chorea in Huntington disease. The KINECT-HD2 study is now also open to new patients who have not participated in the KINECT-HD study.

Huntington disease impacts an estimated 30,000 adults in the United States. Chorea, an involuntary movement disorder, in which people develop abnormal, abrupt or irregular movements, is one of the most common symptoms, affecting roughly 90% of those diagnosed. Current treatments available for chorea are associated with increased risk of depression and suicidality.

"We're pleased to be part of these clinical studies and to see valbenazine move forward in its development as a potential therapy for people living with chorea in Huntington disease," said Andrew Feigin, M.D., Chair of the Huntington Study Group. "We are grateful for our partnership with Neurocrine Biosciences and the possibility of improving the lives of people living with this condition."

Valbenazine was discovered and developed by Neurocrine Biosciences to address the unmet medical needs of people suffering from hyperkinetic movement disorders and was approved by the United States Food and Drug Administration (FDA) in April 2017 for the treatment of adults with tardive dyskinesia. Neurocrine Biosciences is also investigating valbenazine as an adjunctive treatment for schizophrenia and for the treatment of dyskinesia due to cerebral palsy.

About KINECT-HD
KINECT-HD is a Phase 3, randomized, double-blind, placebo-controlled study designed to: evaluate the efficacy of valbenazine as a once-daily treatment to reduce chorea associated with Huntington disease (HD); evaluate the safety and tolerability of valbenazine in patients with HD; and evaluate the ability of wearable movement sensors to detect changes in physical activity (optional activity). The study enrolled adults 18 to 75 years of age who have been diagnosed with motor manifest HD and whom have sufficient chorea symptoms to meet study protocol criteria. For more information on this KINECT-HD study, please visit www.huntingtonstudygroup.org.

About KINECT-HD2
KINECT-HD2 is an open-label, extension study to evaluate the long-term safety and tolerability of valbenazine in patients with chorea in Huntington disease (HD). The 112-week study enrolls adults 18 to 75 years of age who have been diagnosed with motor manifest HD and whom have sufficient chorea symptoms to meet study protocol criteria. For more information on the KINECT-HD2 study, please visit clinicaltrials.gov.

About Chorea in Huntington Disease
Huntington disease (HD) is a hereditary progressive neurodegenerative disorder in which neurons within the brain break down, resulting in motor, cognitive and psychiatric symptoms. Symptoms generally appear between the ages of 30 to 50 and worsen over a 10- to 25-year period. Many people with HD experience chorea, a troublesome involuntary movement disorder, in which people develop abnormal, abrupt or irregular movements. Chorea can affect various body parts and interfere with speech, swallowing, posture and gait. HD is estimated to affect approximately 30,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease. Current treatments available for chorea are associated with increased risk of depression and suicidality.

About Huntington Study Group

Founded in 1993 in Rochester, NY, the Huntington Study Group (HSG) is a not-for-profit organization comprised of the world's first and largest collaborative network of experts in Huntington disease (HD). The mission of the HSG is seeking treatments that make a difference for those affected by HD. With more than 800 credentialed HD experts at over 130 HSG credentialed research sites worldwide, the HSG is a leader in conducting clinical trials for HD. The HSG also offers educational services like CME4HD™ for healthcare professionals and care providers on treating patients with HD. For more information, visit our website www.huntingtonstudygroup.org.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, Neurocrine Biosciences has specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on LinkedIn. (*in collaboration with AbbVie)

Neurocrine Biosciences Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: risks and uncertainties associated with valbenazine development for chorea in Huntington disease (HD), that valbenazine development activities may not be completed on time or at all; risks that valbenazine development activities may not be completed or may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that valbenazine is safe, tolerable or effective in the chorea in Huntington disease (HD) population, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions may not occur or be submitted in a timely manner; risks that valbenazine may not obtain regulatory approval for chorea in Huntington disease (HD), or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding valbenazine; risks that valbenazine may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with the Company's dependence on third parties for development and manufacturing activities related to valbenazine; risks and uncertainties relating to competitive products and technological changes that may limit demand for valbenazine and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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